II. REMARKS

A. Status of the Claims

Claims 1-29 are pending.

B. Claim Rejections- 35 U.S.C. § 103

1. U.S. 2003/0229111 to Oshlack et al.

Claims 1-14, 17-19, 22, 27-29 were rejected under 35 U.S.C. § 103(a) over U.S. 2003/0229111 to Oshlack et al. ("the Oshlack publication").

The rejection is respectfully traversed.

The Manual of Patent Examining Procedure states that "'[a]ll words in a claim must be considered in judging the patentability of that claim against the prior art.'" *MPEP, section 2144.*

Independent claims 1 and 22 recite, in part, that the ratio of naltrexone to hydrocodone in the claimed compositions is "from 0.011:1 to 0.0125:1."

Independent claim 27 recites, in part, that the ratio of naltrexone to hydrocodone in the claimed compositions is "0.0125:1."

Applicants respectfully request that the ratios of naltrexone to hydrocodone recited in independent claims 1, 22 and 27 be considered by the Examiner in judging the patentability of claims 1, 22 and 27 against the Oshlack publication.

Applicants respectfully submit that the Oshlack publication does not describe the claimed naltrexone to hydrocodone ratios, and therefore does not suggests the desirability of the claimed

ratios. Accordingly, the Oshlack publication does not provide a reason for the skilled person to pick the claimed ratios out of infinite number of possibilities encompassed by the Oshlack publication and formulate a composition comprising naltrexone and hydrocodone in the claimed ratios.

In response to the Examiner's statement on page 2 of the Office Action that "when naltrexone is in a dose of 0.056 mg and hydrocodone is 5 mg the ratio is 0.011:1," Applicants respectfully note that the Oshlack publication does not describe a dosage form comprising these amounts of naltrexone and hydrocodone and submit that "[i]t is impermissible to use claimed invention as instruction manual or 'template' to piece together teachings of prior art so that claimed invention is rendered obvious and unpatentable." *See In re Fritch,* 972 F.2d 1260 (C.A. Fed. 1992).

In response to the Examiner's statement on page 4 of the Office Action that "Table 20A [of the Oshlack publication] exemplifies a composition comprising naltrexone hydrochloride in an amount of 0.5 mg and hydrocodone bitartrate in an amount of 5 mg, which meets the limitations of claim 1 ... [and] claim 2." Applicants respectfully note that the ratio of naltrexone to hydrocodone in Table 20A is "0.1:1" (0.5/5=0.1), which is at least eight times higher than the ratio recited in claims 1 and 2. In response to the Examiner's statement on page 3 of the Office Action that "Tables 22A, 23A, 24A, 25A, 26A and 27A [of the Oshlack publication] exemplify a composition comprising naltrexone hydrochloride in an amount of 0.125 mg and hydrocodone amount of 5 mg," Applicants respectfully note that the ratio of naltrexone to hydrocodone based on these amounts is "0.025:1" (0.125/5-0.025), which is at least double the ratio recited in claims 1 and 22. Accordingly, Applicants respectfully submit that the ratios in Tables 20A, 22A, 23A, 24A, 25A, 26A and 27A of the Oshlack publication does not meet the limitations of the naltrexone to hydrocodone ratios recited in independent claims 1, 22 and 27.

In response to the Examiner's statement on page 4 of the Office Action that "it is obvious to vary and/or optimize the amount of hydrocodone and naltrexone provided in the composition, according to the guidance provided by Oshlack et al.," Applicants respectfully reiterate that the

Oshlack publication does not describe the claimed naltrexone to hydrocodone ratios, and therefore neither suggests the desirability of the claimed ratios nor provides a reason for the skilled person to pick the claimed ratios out of infinite number of possibilities encompassed by the Oshlack publication and formulate a composition comprising naltrexone and hydrocodone in the claimed ratios.

With further regard to claims 2-11, Applicants respectfully submit that the Oshlack publication does not provide a reason for the skilled person to formulate a dosage form containing the relative amounts of naltrexone and hydrocodone recited in these claims. In fact, the Examiner stated on page 4 of the Office Action that the Oshlack publication "does not teach compositions with the exact amounts of naltrexone and hydrocodone as listed in claims 2-11 in one composition."

For the foregoing reasons and the reasons presented in the response filed on May 18, 2009, herein incorporated by reference, withdrawal of the rejection is respectfully requested.

2. U.S. 2003/0191147 to Sherman et al. in view of U.S. 2003/0031712 to Kaiko et al.

Claims 1-29 were rejected over the combination of U.S. 2003/0191147 to Sherman et al. and U.S. 2003/0031712 to Kaiko et al. The Examiner stated that "Sherman et al. ... teaches that in preparing a composition, amounts of naltrexone at 0.1% and hydrocodone at 10% are added into a mixture before granulation in Example 15, meeting the limitation of the claimed ratio." Office Action, page 5.

The rejection is respectfully traversed.

Applicants respectfully note that the ratio of naltrexone to hydrocodone in Example 15 of the Sherman publication (i.e., 0.01:1) is at least 10% lower than the lowest ratio recited in independent claims 1 and 22 (i.e., 0.011:1) and is 25% lower than the ratio recited in independent claim 27 (i.e., 0.125:1). Applicants therefore submit that the ratio of naltrexone to hydrocodone

in Example 15 of the Sherman publication does not meet the limitations of the naltrexone to hydrocodone ratios recited in independent claims 1, 22 and 27.

Applicants further submit that the naltrexone to hydrocodone ratio in Tables 1 and 2 of the Kaiko reference also does not meet the limitations of the naltrexone to hydrocodone ratios recited in independent claims 1, 22 and 27. In Tables 1 and 2 in the Kaiko reference, the weight ratio naltrexone per 1 mg of hydrocodone recited is "0.033 to 0.267," with a preferred ratio being "0.050 to 0.200." Applicants respectfully submit that this ratio is outside the ratio recited in independent claims 1, 22 and 27, and is 2.6 times higher[1] than the ratio recited in claims 1, 22 and 27 (i.e., 0.0125:1).

Accordingly, Applicants respectfully submit that the combination of the cited references does not describe the naltrexone to hydrocodone ratios recited in independent claims 1, 22 and 27, and therefore does not suggests the desirability of the claimed ratios.

In response to the Examiner's statement on page 6 of the Office Action that "it is obvious to vary and/or optimize the amount of naltrexone and hydrocodone provided in the composition, according to the guidance provided by Sherman et al.," Applicants respectfully reiterate that the Sherman publication does not describe the claimed naltrexone to hydrocodone ratios, and therefore neither suggests the desirability of the claimed ratios nor provides a reason for the skilled person to pick the claimed ratios out of infinite number of possibilities and formulate a dosage form in accordance with the claimed ratios.

For the foregoing reasons and the reasons presented in the response filed on May 18, 2009, herein incorporated by reference, withdrawal of the rejection is respectfully requested.

[1] 0.033/0.0125=2.64.

III. Conclusion

An early and favorable action is earnestly solicited. According to currently recommended Patent Office policy, the Examiner is specifically authorized to contact the undersigned by telephone in the event that a telephonic interview will advance the prosecution of this application.

Respectfully submitted,
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